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10/538,649	06/10/2005	Michael Huenerbein	3223-104	3729
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ROTHWELL, FIGG, ERNST & MANBECK, P.C.			TOWA, RENE T	
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WASHINGTON, DC 20005			3736	
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			11/26/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/538,649	HUENERBEIN, MICHAEL
	<b>Examiner</b>	<b>Art Unit</b>
	RENE TOWA	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 August 2008.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2-8 and 10-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 2-8 and 10-15 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## DETAILED ACTION

1. This Office action is responsive to an amendment filed August 7, 2008. Claims 2-8 & 10-15 are pending. Claims 10-13 have been amended. Claims 1 & 9 have been cancelled.

### ***Claim Objections***

2. The objections are withdrawn due to amendments.

### **Claim Rejections - 35 USC § 103**

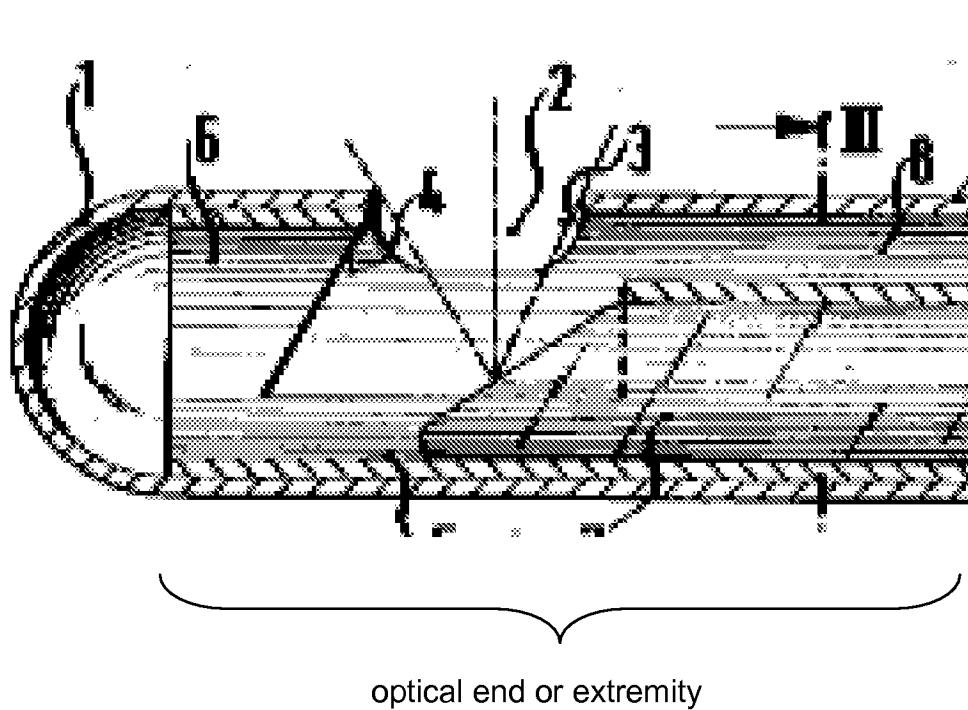
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. **Claims 2, 6, 8, 10 & 13** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Boebel (US 4,620,547).

In regards to **claim 13**, Boebel discloses an optical biopsy instrument comprising:

(a) a substantially cylindrical cannula 1 with a proximal end and a distal end, said cannula 1 having at least one lateral opening 2 in a side surface of the cannula 1, and

(b) an endoscope (5, 6, 7) which is axially movable inside the cannula 1 wherein a clearance formed between the cannula 1 and the endoscope (5, 6, 7) is selected such that a separation of a tissue sample from a tissue is enabled by direct interaction of the optical extremity of the endoscope (5, 6, 7) with the at least one lateral opening 2 by moving at least one of the cannula 1 and the endoscope (5, 6, 7) relative to each other (see figs. 1-3; col. 1, lines 7-15; col. 2, lines 18-34, 38-43 & 50-66).



In regards to **claim 2**, Boebel discloses an optical biopsy instrument characterized in that the at least one lateral opening 2 of the cannula 1 has at least in parts a cutting region 3 at its area being directed towards the distal end (see fig. 2; col. 2, lines 18-34).

In regards to **claim 6**, Boebel discloses an optical biopsy instrument characterized in that an external diameter of the endoscope (5, 6, 7) (i.e. the diameter of cutter 6 of endoscope (5, 6, 7)) substantially corresponds to an internal diameter of the cannula 1 (see fig. 2).

In regards to **claim 8**, Boebel discloses an optical instrument characterized in that the endoscope (5, 6, 7) is a rigid endoscope (5, 6, 7) (see fig. 2).

In regards to **claim 10**, Boebel discloses a method for sampling a tissue sample in duct systems (i.e. the uterus) comprising the steps of:

- (a) introducing an optical biopsy instrument, under endoscopic monitoring, into a duct up to a biopsy site, said optical biopsy instrument comprising
  - a substantially cylindrical cannula 1 with a proximal end and a distal end, said cannula 1 having at least one lateral opening 2 in a side surface of said cannula 1, and
    - an endoscope (5, 6, 7) which is axially movable inside the cannula 1, wherein a clearance formed between the cannula 1 and the endoscope (5, 6, 7) is selected such that a separation of a tissue sample from a tissue is enabled by direct interaction of the optical extremity of the endoscope (5, 6, 7) with the at least one lateral opening 2 by moving at least one of the cannula 1 and the endoscope (5, 6, 7) relative to each other,
- (b) bringing the tissue sample through the at least one lateral opening 2 into the interior of the cannula 1, and
- (c) separating the tissue sample from the rest of the tissue by retracting the endoscope (5, 6, 7) until the at least one lateral opening 2 is closed (see figs. 1-3; col. 1, lines 7-15 & 39-46; col. 2, lines 18-34, 38-43 & 50-68; col. 3, lines 1-6).

*Boebel teaches an optical instrument wherein an inner endoscope comprises both a cutter and an optical system for simultaneously observing or inspecting the area of tissue in question and for extracting the tissue without the instrument or parts thereof having to be removed from the body cavity repeatedly (see col. 2, lines 67-68; col. 3,*

*lines 1-6). Although Boebel teaches an instrument having an optical extremity that may narrowly be dubiously construed to include only a distal end optical window, Boebel discloses an optical biopsy instrument, as described above, that fails to explicitly teach a distal end optical window wherein a separation of a tissue sample from a tissue is enabled by direct interaction of the distal end optical window of the endoscope with the at least one lateral opening.*

However, it is well known to provide an optical instrument with a cutting edge distal end optical window (see abstract; see figs. 6-7; see col. 4, lines 36-48 of US 5,334,150). Since Boebel teaches an inner shaft having a distal end cutting edge for visualizing and cutting the tissue protruding into the aperture; wherein the inner shaft includes a mating cutting edge over the area of the distal lateral aperture by axial displacement of the inner shaft within the cannula (see abstract), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the instrument of Boebel with a distal end optical window cutting edge that serves as a mating cutting edge over the area of the distal lateral aperture by axial displacement of the inner shaft within the cannula such that the endoscope simultaneously helps to visualize and cut the tissue protruding into the aperture.

5. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Hayafuji et al. (US 5,106,364).

*Boebel discloses an optical instrument, as described above in claim 2, that fails to explicitly teach a cutting region formed by a ground.*

However, **Hayafuji et al.** disclose a biopsy instrument comprising at least one

substantially rectangular lateral opening 18; wherein the at least one lateral opening 18 includes a cutting region 41 formed by a ground edge of the at least one lateral opening 18 (see figs. 2-4; col. 5, lines 20-29 & 51-64; col. 6, lines 18-34 & 51-62).

Since both Boebel and Hayafuji et al. teach biopsy devices for cutting tissue wherein a cutting edge of a moveable endoscope or plunger cooperates with a mating cutting edge of a lateral opening in a scissor-like action (see abstracts), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the instrument of Boebel with a ground edge cutting region as taught by Hayafuji et al. in order to cut tissue such that a cutting edge of a moveable endoscope or plunger cooperates with a mating cutting edge of a lateral opening in a scissor-like action.

6. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Lifton ('753).

*Boebel discloses an optical instrument, as described above in claim 13, that fails to explicitly teach that the at least lateral opening that is round, oval, elliptic or rectangular in configuration.*

However, **Lifton** discloses a biopsy instrument characterized in that the at least one lateral opening has a substantially oval or elliptic configuration (see fig. 2; col. 3, lines 18-23).

Since both Boebel and Lifton disclose biopsy instruments comprising lateral opening on a side surface thereof to collect severed biopsy samples into a cavity of the

instrument, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide the instrument of Boebel with an oval lateral opening as taught by Lifton since such a modification would amount to an obvious design choice that would serve the same purpose of collecting severed biopsy samples into a cavity of the instrument.

7. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Yoon (US 4,254,762).

*Boebel discloses an optical instrument, as described above in claim 13, that fails to explicitly teach a transparent distal end wall.*

However, **Yoon** discloses an optical biopsy instrument comprising a transparent distal end wall for forward viewing (see fig. 7; col. 3, lines 58-65; col. 5, lines 41-46; col. 6, lines 43-49 & 55-58).

Since both Boebel and Yoon teach optical biopsy instruments comprising optical system for viewing the tissue region to be biopsied, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide the instrument of Boebel with a transparent end wall as taught by Yoon in order to observe the tissue region to be biopsied via either one of forward or lateral viewing.

8. **Claims 7 & 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Gatto (US 2003/0181823).

*Boebel discloses an optical instrument, as described above in claims 10 & 13, respectively, that fails to explicitly teach a cannula diameter of at most 1.2 mm.*

However, **Gatto** discloses an optical biopsy instrument (see figure 1), characterized in that an external diameter of the cannula is 1.2 mm at most for traversing a mammary gland milk duct (see par 0018 & 0035-0036).

In regards to **claim 7**, since both Boebel and Gatto disclose optical biopsy instruments for use in duct systems, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the instrument of Boebel with a cannula external diameter of at most 1.2 mm as taught by Gatto in order to provide the instrument with the ability to traverse the narrow diameter of the breast ducts (see Gatto, par 0009 & 0018).

In regards to **claim 14**, since both Boebel and Gatto disclose optical biopsy instruments for use in duct systems, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Boebel with a tissue sampled in a mammary as taught by Gatto in order to remove tissue and cells from breast ducts for the detection of breast cancer (see par 0002 & 0018 of Gatto).

9. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Berman et al. (US 6,217,598).

*Boebel discloses an instrument, as described above in claim 13, that fails to explicitly teach a lateral opening with cutting teeth.*

However, **Berman et al.** disclose a biopsy instrument comprising an outer cannula comprising a lateral opening with cutting teeth (218, 220) (see fig. 22; col. 6,

lines 64-67; col. 7, lines 1-18).

Since both Boebel and Berman et al. teach biopsy devices comprising outer and inner cutting members, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide the instrument of Boebel with cutting teeth as taught by Berman et al. in order facilitate tissue cutting by spreading a cut from multiple points of initial puncture (i.e. via the teeth).

10. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Wang (US 4,702,260).

Boebel discloses a method for sampling a tissue sample in duct systems (i.e. the uterus) comprising the steps of:

- (a) introducing an optical biopsy instrument, under endoscopic monitoring, into a duct up to a biopsy site, said optical biopsy instrument comprising
  - a substantially cylindrical cannula 1 with a proximal end and a distal end, said cannula 1 having at least one lateral opening 2 in a side surface of said cannula 1, and
    - an endoscope (5, 6, 7) which is axially movable inside the cannula 1, wherein a clearance formed between the cannula 1 and the endoscope (5, 6, 7) is selected such that a separation of a tissue sample from a tissue is enabled by direct interaction of the optical extremity of the endoscope (5, 6, 7) with the at least one lateral opening 2 by moving at least one of the cannula 1 and the endoscope (5, 6, 7) relative to each other,

- (b) bringing the tissue sample through the at least one lateral opening 2 into the interior of the cannula 1, and
- (c) separating the tissue sample from the rest of the tissue by retracting the endoscope (5, 6, 7) until the at least one lateral opening 2 is closed (see figs. 1-3; col. 1, lines 7-15 & 39-46; col. 2, lines 18-34, 38-43 & 50-68; col. 3, lines 1-6).

*Boebel discloses a method wherein the tissue is separated by moving the endoscope relative to the cannula, as described above, but fails to explicitly teach that the tissue could also be separated by moving the cannula instead, together with a fixed endoscope forward or backward.*

However, **Wang** discloses a biopsy method wherein the tissue is separated by moving a cannula together with a fixed inner cutting element forward or backward to sever tissue (see figs. 2 & 4; col. 4, lines 18-40).

*Boebel teaches an optical instrument wherein an inner endoscope comprises both a cutter and an optical system for simultaneously observing or inspecting the area of tissue in question and for extracting the tissue without the instrument or parts thereof having to be removed from the body cavity repeatedly (see col. 2, lines 67-68; col. 3, lines 1-6). Although Boebel also teaches an instrument having an optical extremity that may narrowly be dubiously construed to include only a distal end optical window, Boebel discloses an optical biopsy instrument, as described above, that fails to explicitly teach a distal end optical window wherein a separation of a tissue sample from a tissue is enabled by direct interaction of the distal end optical window of the endoscope with the at least one lateral opening.*

However, it is well known to provide an optical instrument with a cutting edge distal end optical window (see abstract; see figs. 6-7; see col. 4, lines 36-48 of US 5,334,150). Since Boebel teaches .a method wherein an inner shaft having a distal end cutting edge is used for visualizing and cutting the tissue protruding into the aperture; wherein the inner shaft includes a mating cutting edge over the area of the distal lateral aperture by axial displacement of the inner shaft within the cannula (see abstract), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the instrument of Boebel with a distal end optical window cutting edge that serves as a mating cutting edge over the area of the distal lateral aperture by axial displacement of the inner shaft within the cannula such that the endoscope simultaneously helps to visualize and cut the tissue protruding into the aperture.

Since Boebel and Wang teach biopsy instruments wherein the outer cannula is capable of separating tissue moving a cannula together with a fixed inner cutting element forward or backward to sever tissue, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Boebel as modified above with a step of separating the tissue by moving the cannula as taught by Wang in order to sever the tissue.

11. **Claim 15** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Wang ('260), and further in view of Gatto (US 2003/0181823).

*Boebel as modified by Wang discloses a method, as described above in claim 11, that fails to explicitly teach a method for sampling a tissue sample in a mammary*

*gland milk duct.*

However, **Gatto** discloses an optical biopsy instrument (see figure 1), characterized in that an external diameter of the cannula is 1.2 mm at most for traversing a mammary gland milk duct (see par 0018 & 0035-0036).

Since both Boebel and Gatto disclose optical biopsy instruments for use in duct systems, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Boebel as modified by Wang above with a tissue sampled in a mammary as taught by Gatto in order to remove tissue and cells from breast ducts for the detection of breast cancer (see par 0002 & 0018 of Gatto).

#### ***Response to Arguments***

12. Applicant's arguments filed August 7, 2008 have been fully considered but they are not persuasive. Applicant argues that Boebel fails to teach an endoscope selected to enable tissue sample separation by direct interaction of a lateral opening with the endoscope. This argument has been considered but has not been deemed persuasive.

In regards to the Applicant's argument, the Examiner respectfully traverses. The Examiner notes that Boebel does teach an endoscope that the Examiner has indicated to be numerals (5, 6, 7) contrary to the Applicant's reference and insistence that only the element numeral 7 could or should be construed as the endoscope. Yet again, the Examiner could not disagree more. First, the Examiner notes that MPEP, section 2111.01 (III) reads as follows:

"[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips v. AWH Corp., \*415 F.3d 1303, 1313<, 75 USPQ2d 1321>, 1326< (Fed. Cir. 2005) (en banc). Sunrace Roots Enter. Co. v. SRAM Corp., 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003)(“In the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art.”). It is the use of the words in the context of the written description and customarily by those skilled in the relevant art that accurately reflects both the “ordinary” and the “customary” meaning of the terms in the claims. Ferguson Beauregard /Logic Controls v. Mega Systems, 350 F.3d 1327, 1338, 69 USPQ2d 1001, 1009 (Fed. Cir. 2003) [Emphasis added]

Contrarily, the Applicant’s position is directly and absolutely opposite to the meaning that the term "endoscope" would have to one of ordinary skill in the art at the time of the invention. As shown in claim 1 of exemplary US Patent 5,632,717, which reads as follows:

**1. An endoscope comprising**

an endoscope tube;

**an illumination system** disposed within said endoscope tube;

a viewing system disposed within said endoscope tube and including a viewing window at a distal end;

**a penetrating member** disposed at least partly within said endoscope tube and having a distal end for penetrating anatomical tissue, wherein said endoscope tube, illumination system and viewing system cooperate to define a blunt distal end of said endoscope with a smooth, rounded configuration and said penetrating member is movable between a retracted position where said distal end of said penetrating member is proximally spaced from said blunt distal end of said endoscope to permit non-traumatic tissue contact with said blunt distal end and an extended position where said distal end of said penetrating member protrudes beyond said blunt distal end of said endoscope to penetrate anatomical tissue, said penetrating member being laterally offset from said viewing window in said retracted position; and

a control mechanism coupled with said penetrating member, said control mechanism being selectively operable to move said penetrating member between said retracted and extended positions [Emphasis added].

An endoscope is not necessarily limited to the optical system alone as repeatedly and wrongfully argued by Applicant. To the contrary, an endoscope may include other elements such as a cutting or penetrating member as taught in the exemplary patent above. Indeed, Boebel teaches a device that comprises an inner shaft 5 having an

integrally formed extension or ring of a larger diameter acting as a cutter 6 (see col. 2, lines 29-37). As such, col. 2, lines 29-34 reads as follows:

**The cutter 6** is joined fixedly or releasably to the untwistable and axially displaceable inner shaft 5 by means known per se such as screw-threads or the like and **in the case of the illustrated example is formed by an integral annular extension of the inner shaft 5.**

The inner shaft 5 further includes an optical system 7 coupled therewith, which optical system further comprises a lateral objective (see col. 2, lines 18-25, 38-43 & 51-56). It is thus apparent that the inner shaft 5, cutter 6, and optical system 7 integrally form the "endoscope." As such, the Examiner submits that Boebel fully teaches an endoscope.

Similarly, Boebel teaches an endoscope having a distal optical end that is adapted for cutting tissue. The Examiner notes that the limitations "optical end of the endoscope" does not necessarily refer to the optical window of the endoscope or the tip of the optical system; rather, the "optical end" could pertain to the end, side or extremity of the endoscope as a whole. As such, the Examiner submits that Boebel teaches an endoscope having a distal optical end that is adapted for cutting tissue in that the same end that endoscope end that carries the optical system 7 also carries the cutter 6.

Moreover, the Applicant makes several arguments contending that "the optical end" potentially could be dull or blunt. However, none of the claim language clarifies this alleged distinction. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a blunt or dull optical distal end) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from

the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In view of the foregoing, the rejections over Boebel are maintained.

***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,334,150 to Kaali discloses a visually directed trocar for laparoscopic surgical procedures.

US 4,900,300 to Lee discloses a surgical instrument.

US 5,632,717 to Yoon discloses a penetrating endoscope.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. T./  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736